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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,842	11/28/2000	Robert Chalifour	14445-501	6146

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EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/724,842	Challfour et al.
Examiner	**Art Unit**
Sharon L. Turner, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 9-17-01

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 46-103 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 46-103 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. The amendment filed 9-17-01 has been entered into the record and has been fully considered.

2. Claims 46-103 are pending.

Improper Markush

3. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompass multiple distinct peptides, as identified and claimed, which fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

Election/Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 46-69 and 93-98 in part drawn respectively to distinct methods of treating and/or preventing with a peptide, classified for example in class 514, subclass 2.

II. Claims 70-92 and 99-103 in part drawn respectively to distinct compositions, classified for example in class 530, subclass 350.

5. Furthermore, in addition to the election of one of the above II groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments (peptides) to which the claims will be restricted in accordance with the elected group:

The patentably distinct peptides of the claimed invention include peptides which interact with at least one region of an amyloid protein selected from 1) C-terminal region, 2) β-sheet region, 3) GAG-binding site region, 4) cellular adherence region, 5)-67) peptides corresponding respectively to amino acids of SEQ I D NO's:1-63, peptides of 68) Aβ(1-42), 69) beta sheet region of IAPP (24-29), 70) β_2 microglobulin, 71) amyloid A protein, 72) a prion-related protein wherein the prion-related protein (amino acid sequence) is defined, and 73) macrophage adherence region (10-16) .

6. The inventions are distinct, each from the other because of the following reasons:

7. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as Groups 1-73 constitute patentably distinct inventions for the following reasons. Each of the polypeptides has unique structural features which requires a different search of the prior art. The inventions indicated as Groups 1-73 differ in structure and function as they are composed of divergent amino acids and are differentially able to bind and mediate biological functions. A reference to one element would not constitute a reference to

another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

8. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the peptide can alternatively be practiced with an alternative peptide or antibody and the peptide can be used in the alternative process of a detection assay.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-II above and a single molecular embodiment (peptide) from designated Groups 1-73 above to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-II nor 1-73 are species election requirements; rather each of I-II and 1-73 are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

13. This application contains claims directed to the following patentably distinct groups of species of the claimed invention:

Species 1) selected from R' or N-terminal substituents of A) hydrogen, B) lower alkyl group acyclic, C) lower alkyl group cyclic, D) aromatic, E) heterocyclic, F) unsubstituted amino groups and G) substituted amino groups.

Species 2) selected from R'' or C-terminal substituents of A) hydroxy, B) alkoxy, C) aryloxy, D) unsubstituted amino groups and E) substituted amino groups.

Species 3) disease selected from A) Cruetzfeld-Jakob, B) familial amyloid neuropathy, C) hereditary spongiform encephalopathy, D) scrapie, E) bovine spongiform encephalopathy, F) light chain-related amyloidosis, G) secondary amyloidosis, H) Type I diabetes, I) Type II diabetes, J) primary amyloidosis, K) prion disease, L) dialysis related amyloidosis, M) Alzheimer's and N) cerebral anyloid angiopathy.

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of species groups 1-3 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 46, 56, 70, 81, 93 and 99 are generic.

Applicant is advised that a reply to this requirement must include an identification of a single species from each of the groups of species specified in 1-3 that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
February 12, 2002

Gary L. Kunz

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600